

14 TITLE

Viral particles and their use 13

PROJECT NO.

BOOK NO.

Investigator: H. B. C. Date: 11/11/05
Notebook page #: 515/11 Microsphere lot #: 50591-11Microsphere Production
Process Room ConditionsRoom Temp: 22°C
Room Humidity: 51.5% RH

Polymer Preparation

Polymer Type 1: PEG-PLGA
Source & Lot no.: BPTE Lot # 2041-14-14
Mass (g): 3.60 g
Polymer type 2: D.L. PLA
Source & Lot no.: KE Lot # 31028
Mass (g): 3.61 g
Solvent Type: Acetone
Source & Lot no.: EM lot no 31068
Volume: 70 mL
Surfactant type: Levulin
Surfactant conc: 25 mg
Observation method: 360°
Dissolution Temp: Room Temp
Dissolution Time: 15 min
Extraction 1: H₂O
Source & Lot no.: House DE
Amount (mL): 20 mLComments:
Similar emulsion created in water as follows:
100 g in 40 mL of H₂O. Added to polymer solution.

Aeration Methodology

Sonication: None
Hom type: None
Frequency: None
Power: None
Temperature: None
Time: None
Time and spray: None
Spraying: None
Gas type: None
Gas pressure: None
Temperature: None
Time: None
Time and spray: None
Homogenization: VIRTIS
Blade type: Macro ultra-fine generator
Time: minutes (111)
Speed: 2.0 rpm (40)
Temperature: Ice bath
Time and spray: minutes
Comments:

Spray Conditions

Chemistry Proc.: Emulsion production. Microsphere prep.
Nozzle type: 0.7 mm standard, vent D
Gas Pressure: 99 psi
Gas Flow rate: 600 L/H
Gas type: Medical grade
Feed Pressure: 112 psi
Inlet Temp: 22°C
Start Time: 1:16
Finish Time: 1:28
Mass (g): 1613-16.71 ± 1.97
Yield (g): 1.7%

Process Conditions

Start 1:17 Middle 1:27 Finish 1:28
Outlet Temp: 29°C 29°C 29°C
Filter Vacuum: -40 mmHg -10 mmHg -10 mmHgComments:
Did not get inlet tube as full down up 2 previous batches.

Drying Methodology

Type: Lyophilization VIRTIS
Total dry time: 24 hours
Mass recovered: gallons (8,445-16.71) ± 1.97%
Yield (g): 1.805 g - 1.7%
Comments:
14% in 24 hours as before. Dried from 1:25 to 2:35
At 2:35, 14% weight recovered. Placed back on 12/11/05
Revised for 12/11/05 at 12:00, 12:00

Sizing Methodology

Room Temp: None
Room Humidity: None
Screening Time: None
Screen size: None
Screen type: None
Product recovered: None
Yield (g): None
Comments:

SECURITY SENSITIVE PROPERTY

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Work continued to Page 15

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80 TITLE

TJU Study For [REDACTED]

PROJECT NO

Sample ID	Material	Weight (g)	Volume (mL)	Concentration (mg/mL)	Preparation Comments	Integrity	Out Date
941082	VI	30	1.0	3.0			
941083	VI	30	1.0	3.0			
941084	VI	30	1.0	3.0			
941085	VI	30	1.0	3.0			
941086	VI	30	1.0	3.0			
941087	VI	30	1.0	3.0			
941088	VI	30	1.0	3.0			
941089	VI	30	1.0	3.0			
941090	VI	30	1.0	3.0			
941091	VI	30	1.0	3.0			
941092	VI	30	1.0	3.0			
941093	VI	30	1.0	3.0			
941094	VI	30	1.0	3.0			
941095	VI	30	1.0	3.0			
941096	VI	30	1.0	3.0			
941097	VI	30	1.0	3.0			
941098	VI	30	1.0	3.0			
941099	VI	30	1.0	3.0			
941100	VI	30	1.0	3.0			

Sample ID	Material	Weight (g)	Volume (mL)	Concentration (mg/mL)	Preparation Comments	Integrity	Out Date
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941083	VI	30	1.0	3.0			
941084	VI	30	1.0	3.0			
941085	VI	30	1.0	3.0			
941086	VI	30	1.0	3.0			
941087	VI	30	1.0	3.0			
941088	VI	30	1.0	3.0			
941089	VI	30	1.0	3.0			
941090	VI	30	1.0	3.0			
941091	VI	30	1.0	3.0			
941092	VI	30	1.0	3.0			
941093	VI	30	1.0	3.0			
941094	VI	30	1.0	3.0			
941095	VI	30	1.0	3.0			
941096	VI	30	1.0	3.0			
941097	VI	30	1.0	3.0			
941098	VI	30	1.0	3.0			
941099	VI	30	1.0	3.0			
941100	VI	30	1.0	3.0			

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941096	VI	30	1.0	3.0			
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941098	VI	30	1.0	3.0			
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941085	VI	30	1.0	3.0			
941086	VI	30	1.0	3.0			
941087	VI	30	1.0	3.0			
941088	VI	30	1.0	3.0			
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941091	VI	30	1.0	3.0			
941092	VI	30	1.0	3.0			
941093	VI	30	1.0	3.0			
941094	VI	30	1.0	3.0			
941095	VI	30	1.0	3.0			
941096	VI	30	1.0	3.0			
941097	VI	30	1.0	3.0			
941098	VI	30	1.0	3.0			
941099	VI	30	1.0	3.0			
941100	VI	30	1.0	3.0			

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Samples weighed by Howard in Dry Box
 on [REDACTED]. All but the 941082 and 941083
 samples sent to Friesberg on [REDACTED] by Air Mail
 on dry ice / gel pack

SCIENTIFIC BUDGET PRODUCTIONS CHICAGO 60646 Made in USA

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Henry T. Bol

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Work continued to Page 81/100

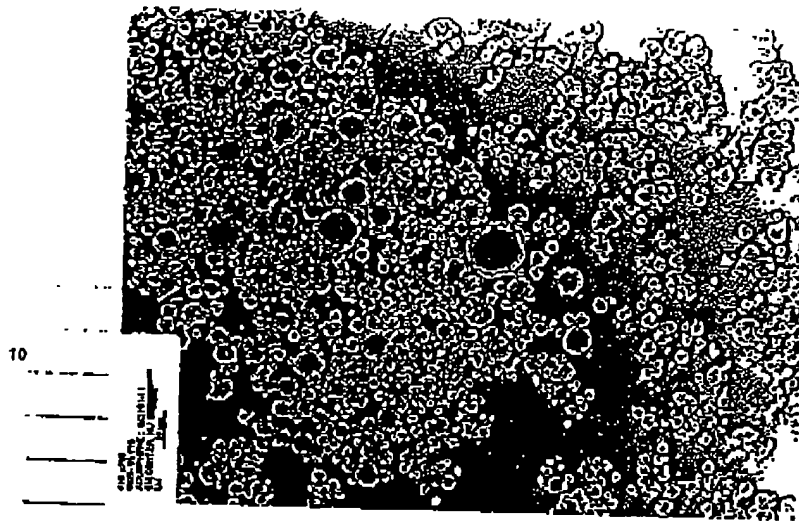
DATE

DATE

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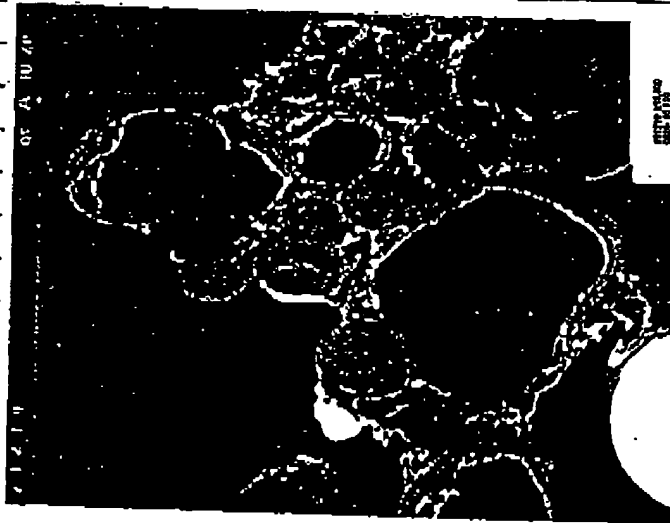


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Handwritten signature/initials

SCIENTIFIC IMAGING PRODUCTIONS CHICAGO ILLINOIS Made in USA

SIGNATURE *James C. Shanks*
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Harry F. Paul

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PROJECT NO

VIA CONTAINER ...

Atmosphere

Notes

All samples will be prepared by weighing and modification.

All samples will be prepared in 30 ml. volumetric vials. Empty 20 ml. volumetric vials will be brought.

Saline (0.9%) will be used instead of water for the bulk filling in the pumping system. Preweighed samples of 16.2 g of NaCl will be brought out, and added to 1800 ml. with water in a bottle. Two more bottles will be used as TPL. A total of 36 NaCl vials will be brought.

Vehicle 1 = 0.9% NaCl 20.7% glycerol — reversed

Vehicle 2 = 0.9% NaCl 54.6 mg/ml. needed

1) System eventually came as experiment, except 500ml saline in body

2) Vehicle 2 (VF) was used

3) Younger who did the entire study

4) After injection of sample, sample was shared, flow rate was then increased to 500-800ml/min until echogenic material detected by the oscilloscope, flow rate then dropped to 100-200 ml/min.

5) The later window moved dramatically with each pulse

6) Tubing was manipulated to remove bubbles. At least once (prior to injection 4) this resulted in change of alignment. At that one detection time, the machine was retriggered.

7) Cleaning procedure: (1) water pumped to remove all material, then saline pumped in (2) bottle emptied, saline added + pumped through.

(2) System pumped dry, saline pumped in

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Work. Cont.

88/84/105

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400-30

Subject	Sample ID/Amount	Exposure Preparation	Echogenicity Index	Echogenicity Over Time	Spun
1	ALB-0.06	NA (PABST)	no - 100mm		NO
2	ALB-0.50	NA (PABST)	almost all white		NO
3	ALB-0.75	NA	almost all white		NO
4	ALB-1.00	NA	almost all white		NO
5	3-VF-12	1/52/1/10	not echogenic		NO
6	4-VF-12	1/52/1/10	not echogenic		NO
7	5-VF-12	1/52/1/10	not echogenic		NO
8	6-VF-12	1/52/1/10	not echogenic		NO
9	7-VF-12	1/52/1/10	not echogenic		NO
10	8-VF-12	1/52/1/10	not echogenic		NO
11	9-VF-12	1/52/1/10	not echogenic		NO
12	10-VF-12	1/52/1/10	not echogenic		NO
13	11-VF-12	1/52/1/10	not echogenic		NO
14	12-VF-12	1/52/1/10	not echogenic		NO
15	13-VF-12	1/52/1/10	not echogenic		NO
16	14-VF-12	1/52/1/10	not echogenic		NO
17	15-VF-12	1/52/1/10	not echogenic		NO
18	16-VF-12	1/52/1/10	not echogenic		NO
19	17-VF-12	1/52/1/10	not echogenic		NO
20	18-VF-12	1/52/1/10	not echogenic		NO
21	19-VF-12	1/52/1/10	not echogenic		NO
22	20-VF-12	1/52/1/10	not echogenic		NO
23	21-VF-12	1/52/1/10	not echogenic		NO
24	22-VF-12	1/52/1/10	not echogenic		NO
25	23-VF-12	1/52/1/10	not echogenic		NO
26	24-VF-12	1/52/1/10	not echogenic		NO
27	25-VF-12	1/52/1/10	not echogenic		NO
28	26-VF-12	1/52/1/10	not echogenic		NO
29	27-VF-12	1/52/1/10	not echogenic		NO
30	28-VF-12	1/52/1/10	not echogenic		NO
31	29-VF-12	1/52/1/10	not echogenic		NO
32	30-VF-12	1/52/1/10	not echogenic		NO

400-30

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25	23-VF-12	1/52/1/10	not echogenic		NO
26	24-VF-12	1/52/1/10	not echogenic		NO
27	25-VF-12	1/52/1/10	not echogenic		NO
28	26-VF-12	1/52/1/10	not echogenic		NO
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30	28-VF-12	1/52/1/10	not echogenic		NO
31	29-VF-12	1/52/1/10	not echogenic		NO
32	30-VF-12	1/52/1/10	not echogenic		NO

Shirley
Ruehl
TJW
on [redacted]

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